

REMARKS

Summary is noted of the restriction requirement under 35 U.S.C. §121 among Invention I (claims 1-5, 85-201, 260-263), and Invention II (claims 6-16, 29-38, 50-71), and Invention III (claims 17-28, 39-49, 72-84, 202-259). Applicant hereby affirms the election to prosecute in this application the provisionally-elected Invention I, and includes as readable thereon claims 1-5, 85-201 and 260-263. Applicant is retaining the non-elected claims in this application, unexamined, pending allowance of a generic or linking claim.

Claims 260-263 have been rejected under the judicially-created doctrine of obviousness-type double patenting over claims 1-8 of U.S. Patent No. 6,599,313.

Applicant is submitting herewith a Terminal Disclaimer to obviate this basis for rejection of claims 260-263 which are therefore respectfully submitted to be patentable to Applicant.

Claims 1, 96, and 126 have been rejected under 35 U.S.C. §102(e) as being anticipated by Wilk '861, or in the alternative under 35 U.S.C. §103(a) as being obvious over Wilk '861 in view of Leckrone '405. This rejection is respectfully traversed with respect to these claims as amended herein.

Specifically, these claims as amended herein merely to clarify the issues now recite in various ways “endoscopically creating from outside the blood vessel an opening into the blood vessel at a selected location; and endoscopically forming

an anastomosis between the blood-conveying conduit and the opening created into the blood vessel at the selected location”, and “advancing the delivery device toward the anastomosis site from outside the vessel while the graft is located within the passageway of the delivery device”, and “the delivery device is a laparoscope”.

These aspects of the claimed invention facilitate vessel grafting without traversing the vessel to an astomotic site. These aspects of the claimed invention are not disclosed or even suggested by either Wilk ‘861 alone or considered in the combination with Leckrone ‘405 as proposed by the Examiner. At best, Wilk ‘861 discloses conducting a bypass operation through the vascular system that leads to a bypass site in a coronary artery (col. 3, lines 1-4, as lines 62-65). There is no suggestion found in this reference of performing a vessel bypass from outside the vessel in which the bypass is formed. Nor does the intravascular surgical procedure disclosed by Leckrone ‘405 proceed to an operative site in a targeted vessel otherwise than through or along the targeted vessel. There is no suggestion or disclosure in this reference for proceeding to a surgical site on a targeted vessel from outside the vessel. And, the procedures disclosed in this reference for removing plaque or stenotic debris from a wall of a vessel offer no incentive or motivation for forming an opening in a vessel wall (less so from outside the vessel) via a catheter (or endoscope or laparoscope) disposed within the vessel. It is

therefore respectfully submitted that neither Wilk '861 alone anticipates amended claims 1, or 96 or 126, nor that this reference in combination with Leckrone '405 are capable of establishing even a *prima facie* basis (contrary to the Examiner's assertion) from which a proper determination of obviousness can be made. It is therefore respectfully submitted that amended claims 1, 96 and 126 are patentably distinguishable over the cited art.

Claim 261 has been rejected under 35 U.S.C. §102(e) as being anticipated by Wilk '861. This rejection is respectfully traversed with respect to this claim as amended herein.

This claim has been amended herein merely to clarify the distal or first portion and proximal or second portion of the recited medical instrument. As amended, claim 261 specifically recites "guiding the distal end portion of said medical instrument through an opening formed in said circulatory system to extend a distal portion of said medical instrument outside of said circulatory system with a proximal portion of said medical instrument located within said circulatory system", or "advancing said implantable medical apparatus within said medical instrument located outside of said circulatory system".

These aspects of the claimed invention promote vascular surgery at a remote location from outside of the segment of the circulatory system being operated upon.

These aspects of the claimed invention are not disclosed or even suggested by Wilk '861 which merely discloses installing a stent within a blood vessel into a cardiac chamber from within the circulatory system (i.e., intravascularly). There is no disclosure or even any suggestion in this reference for installing an implantable apparatus into a circulatory system from outside the circulatory system in a manner as claimed by Applicant. It is therefore respectfully submitted that claim 261 is not anticipated by, but instead is clearly patentably distinguishable over, the cited art.

Claims 1 and 2 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Donaldson '068 in view of Leckrone '405. This rejection is respectfully traversed with respect to these claims as amended herein.

Specifically, these claims as amended herein merely to clarify the issues now recite “endoscopically creating from outside the blood vessel an opening into the blood vessel at a selected location; and endoscopically forming an anastomosis between the blood-conveying conduit and the opening created into the blood vessel at the selected location”, and “the blood vessel is the aorta; and the selected location is above the iliac arterial bifurcation of the aorta”.

These aspects of the claimed invention promote vascular surgeries in a manner not disclosed or even suggested by the cited references considered either alone or in the combination proposed by the Examiner. Specifically, the Examiner correctly notes that Donaldson '068 fails to disclose any endoscopic procedures for

forming an opening in a vessel or for forming an anastomosis between a conduit and the vessel. Nor does this reference disclose anastomosing to the aorta above the bifurcation of the aorta, as claimed.

And, Leckrone '405 discloses intravascular deployment of apparatus for removing an occlusion or accumulated plaque in the transporting vessel, with no hint of forming an opening into the vessel from outside the vessel using endoscopic techniques. Nor is there any incentive or motivation found in these references for applying an intravascular catheter (with laser optics and balloon and vacuum channel) of Leckrone '405 in any manner to anastomosing a bypass conduit to a blood vessel at an opening therein formed endoscopically from outside the vessel, as claimed. And, the passage of the abstract and of columns 6 and 7 of Leckrone '405 referred to by the Examiner merely pertain to intravascular manipulation of a catheter for removing plaque or occluding material that obstructs the vessel, and offers no hint of an arteriotomy and no support, as the Examiner contends for establishing even a *prima facie* basis from which a proper determination of obviousness can be made. At best, the combination of these references proposed by the Examiner constitutes an improper hindsight reconstruction of these references well beyond their operational purposes using instructions found, not in these references, but found instead only in Applicant's own disclosure. It is

therefore respectfully submitted that claims 1 and 2 as amended are patentably distinguishable over the cited art.

Claims 3, 4, 93, 94, 108, 123, 124, 131-140, 149, 150, 152, 165, 166, 168, 181, 194, 195 and 197 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Donaldson '068 and Leckrone '405 (as a secondary reference) as applied, above, to claims 1 and 2 further in view of Wilk '861. This rejection is respectfully traversed with respect to these claims as amended herein.

These claims as amended merely to clarify the issues now variously recite “advancing an end portion of the blood-conveying conduit through the lumen of the endoscope”, or “advancing the delivery device toward the anastomosis site from outside the vessel while the graft is located within the passageway of the delivery device”, or “moving the delivery device away from the arteriotomy defined in the wall of the aorta”, or “advancing the delivery sheath from outside the aorta toward the arteriotomy”, or “advancing the delivery sheath toward the arteriotomy from outside the aorta while the graft is located within the interior space of the delivery sheath”.

Additionally, these claims various recite “the delivery sheath holds the graft in a linear configuration” (or, rolled), or “the aorta attachment end is removed from the interior space of the delivery sheath prior to removal of said another vessel attachment end from the interior space”, where the delivery device is variously

defined as a laparoscope, a vessel is variously recited to be an artery or the aorta, and a graft or conduit is delivered through the delivery device.

These aspects of the claimed invention are not disclosed or even suggested by the references considered either alone or in the combination proposed by the Examiner. Specifically, the deficient disclosure of Wilk '861 offers no hint or suggestion of delivering a conduit or graft to an anastomosis site or opening in a vessel from outside the vessel, as additionally detailed in the above Remarks. Similarly, Leckrone '405 delivers no graft or conduit to such a site on a vessel, and functions only within a vessel merely to remove plaque or occlusive debris. And Donaldson '068 was recognized by the Examiner in earlier comments as failing to disclose any endoscopic or laparoscopic procedure in bypassing a portion of a diseased aorta. Thus, there is no disclosure in these references that would offer any incentive or instruction for combining the references in the manner proposed by the Examiner in order to yield any resemblance to the surgical procedures performed from outside the vessel in the manner as now claimed by Applicant. It is therefore respectfully submitted that claims 3, 4, 93, 94, 108, 123, 124, 131-140, 149, 150, 152, 165, 166, 168, 181, 194, 195 and 197 as amended herein are now patentably distinguishable over the cited art.

Claims 85-92, 95, 97-107, 109-122, 125, 127-130, 141-148, 151, 153-164, 167, 169-180, 182-193, 196, 198-201, 260 and 262 are rejected under 35 U.S.C.

§103(a) as being unpatentable over Wilk '861 alone. This rejection is respectfully traversed with respect to these claims as amended herein.

These claims were amended herein merely for clarification variously recite “advancing the delivery device toward the anastomosis site from outside the vessel while the graft is located within the passageway of the delivery device”, or “the aorta attachment end is removed from the passageway of the delivery device prior to removal of the other vessel attachment end from the passageway”, or “the removing step includes the step of moving the delivery sheath away from the opening defined in the blood vessel”, or “advancing a medical instrument upstream within a blood vessel of said body from a location downstream of the occluded segment”, or “advancing said medical instrument within said circulatory system of said body proceeds toward said occluded segment from a location downstream of the occluded segment”.

In addition, the dependent claims now depend from claims that are submitted to be allowable as variously amended herein, and are submitted to be allowable for that reason in addition to specifically defining various aspects of the procedural steps of advancing a delivery device, removing the delivery device, positioning ends of the graft or conduit first to an artery or aorta, advancing upstream toward an occlusion rather than downstream through the occlusion, and the like.

These aspects of the claimed invention are not disclosed or even suggested by Wilk '861 alone which at best delivers a stent intravascularly and then positioning a first end of the stent in a cardiac chamber and then a second end in an artery as the delivery device is removed in opposite sequence and diverse procedure from Applicant's method as now claimed. And, there is no hint of instruction or motivation contained in this reference for modifying the disclosure as the Examiner suggests to reverse procedural sequences in order to provide even a *prima facie* basis from which a proper determination of obviousness can be made. It is therefore respectfully submitted that claims 85-92, 95, 97-107, 109-122, 125, 127-130, 141-148, 151, 153-164, 167, 169-180, 182-193, 196, 198-201, 260 and 262 are now patentably distinguishable over the cited art.

Allowance of claim 5 is noted with appreciation.

Support for amendments as set forth herein merely to clarify claim recitations is contained in the specification, for example, with reference to the descriptions of Figures 6-8, 12-15 and 26-30, and in the claims as originally filed in this application.

Responsive to the Examiner's request, Applicant is submitting herewith a list of pending applications, but declines to provide copies of the claims in such applications in consideration that such claims, which would not otherwise be publicly available, may become part of the prosecution history of a patent that may

issue on this application. In the event the Examiner is unable to retrieve copies of the pending claims in the listed applications, Applicant shall make copies of these claims available under a procedure by which those pending claims may remain publicly unavailable.

Reconsideration and allowance of all elected claims (including claim 263 not discussed) are respectfully requested.

Respectfully submitted,
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ATTACHMENTS:

Terminal Disclaimer

List of pending related applications

Information Disclosure Statement